

WHAT IS CLAIMED IS:

1. A method for revascularization, said method comprising the step of:

5 a) forming an extravascular passageway between a first location on a blood vessel and a second location on a blood vessel, such that blood having a pO_2 of at least 50 will flow through said extravascular passageway.

10 2. The method of Claim 1 wherein said first location and said second location are on at least one blood vessel of the heart.

3. The method of Claim 1 wherein said first location and said second location are on the same blood vessel.

4. The method of Claim 1 wherein said first location and said second location are on different blood vessels.

5. The method of Claim 4 wherein said blood vessels are a artery and a vein.

20 6. The method of Claim 4 wherein said blood vessels are a vein and a vein.

7. The method of Claim 4 wherein said blood vessels are an artery and an artery.

25 8. The method of Claim 4 wherein a plurality of said extravascular passageways are formed between said blood vessels.

30 9. The method of Claim 1 wherein said extravascular passageway is formed for the purpose of bypassing an obstructed, injured or diseased segment of a blood vessel.

10. The method of Claim 1 wherein said first location is on an artery and said second location is on a vein, such that blood will flow from said artery, through said extravascular passageway, and into said vein.

35 11. The method of Claim 10 wherein blood which has entered the vein through said extravascular passageway is

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subsequently caused to flow through said vein so as to retroperfuse tissue through the venous vasculature.

12. The method of Claim 11 wherein said blood is caused to flow through the vein so as to retroperfuse tissue through venous vasculature by:

b) blocking said vein at a location adjacent said extravascular passageway to cause blood which flows into said vein through said extravascular passageway to subsequently flow through said vein in a direction which will cause said retroperfusion of tissue through the venous vasculature.

13. The method of Claim 1 wherein the extravascular passageway formed in step a is a primary extravascular passageway formed between a first blood vessel and a second blood vessel such that blood having a pO_2 of at least 50 will flow from the first blood vessel, through said extravascular passageway, and into the second blood vessel.

14. The method of Claim 13 wherein said method further comprises the step of:

b) forming at least one secondary extravascular passageway between said second blood vessel and another blood vessel of the heart such that blood which has entered the second blood vessel through the first extravascular passageway will subsequently flow into another blood vessel through said secondary extravascular passageway.

15. The method of Claim 14 wherein said blood is caused to flow into the other blood vessel through the secondary extravascular passageway by:

c) blocking the second blood vessel at a location adjacent the second extravascular passageway to cause said blood to flow from said second blood vessel through said second extravascular passageway and back into said other blood vessel.

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16. The method of Claim 1 wherein at least one of said first and second locations are on a blood vessel which is part of a system of blood vessels wherein an obstructed, injured or diseased segment of a blood vessel is present.

17. The method of Claim 1 wherein step a of said method is carried out by:

i) providing a passageway-forming catheter device comprising an elongate flexible catheter body having a tissue-penetrating element passable therefrom so as to penetrate through the wall of a blood vessel in which said catheter body is inserted;

ii) inserting said catheter body into the vasculature and positioning said catheter body such that the tissue-penetrating element is located adjacent the location at which said extravascular passageway is to be formed;

iii) passing said tissue-penetrating element from said catheter body so as to form said extravascular passageway in accordance with step a of said method.

18. The method of Claim 17 wherein step i further comprises:

providing an orientation means for locating said first and second locations and for orienting the catheter device such that the tissue-penetrating element of the catheter will pass from said first location to said second location, thereby forming said extravascular passageway between said first location on a blood vessel and said second location on a blood vessel.

19. The method of Claim 17 wherein the tissue-penetrating element of the device provided in step i further incorporates a lumen through which a guide wire may be passed upon creation of said extravascular

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passageway by said tissue-penetrating element, and wherein said method further comprises the step of:

5 passing a guide wire through said lumen and allowing said guide wire to remain extended through said extravascular passageway following extraction and removal of said catheter, to thereby provide for subsequent advancement of one or more other apparatus through said passageway, over said guide wire.

10 20. A method coronary revascularization in a mammalian heart having arteries and veins formed therein, said method comprising the steps of:

15 providing a passageway-forming catheter adapted to form an extravascular passageway between two blood vessels;

20 inserting said catheter into a peripheral blood vessel and advancing said catheter into a blood vessel of the heart;

25 utilizing said catheter to form at least one primary extravascular passageway between the blood vessel of the heart in which said catheter is positioned and another blood vessel of the heart, such that blood will flow from one of the blood vessels, through the extravascular passageway, and into the other blood vessel.

30 21. The method of Claim 20 wherein said at least one passageway is formed between an artery of the heart and a vein of the heart such that blood from the artery will flow through at least one of said extravascular passageway(s) into the vein of the heart.

35 22. The method of Claim 21 wherein arterial blood which as flowed from the artery of the heart into the vein of the heart is subsequently caused to flow through the vein so as to retroperfuse cardiac tissues through the cardiac venous vasculature.

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23. The method of Claim 22 wherein said arterial blood is caused to flow through the vein so as to retroperfuse cardiac tissue through the cardiac venous vasculature by blocking flow through the vein in an opposite direction, at a location adjacent an extravascular passageway.

24. The method of Claim 21 wherein the method further comprises:

utilizing said catheter to form at least one secondary extravascular passageway from said vein of the heart to an artery of the heart such that arterial blood which has entered said vein of the heart will subsequently flow through said at least one secondary extravascular passageway and into an artery of the heart, so as to profuse cardiac tissues through the cardiac arterial vasculature.

25. The method of Claim 20 wherein said method is carried out for the purpose of bypassing an obstructed, injured or disease-affected segment of an artery of the heart.

26. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein and a Left Anterior Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Circumflex Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Left Anterior Descending Artery and the Anterior Interventricular Vein;

ii. forming a secondary extravascular passageway between the Great Cardiac Vein and the Circumflex Artery at a location downstream of the obstructed, injured or disease-affected segment thereof; and,

iii. causing blood to flow from the Left Anterior Descending Artery through the primary

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extravascular passageway, through the Anterior Interventricular Vein into the Great Cardiac Vein, and through the secondary extravascular passageway into the Circumflex Artery, downstream of the obstructed, injured or disease-affected segment thereof.

27. The method of Claim 26 wherein step iii is accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the primary extravascular passageway.

28. The method of Claim 27 wherein step iii is further accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the secondary extravascular passageway.

29. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein, and a Left Anterior Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Left Anterior Descending Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Circumflex Artery and the Great Cardiac Vein;

ii. forming a secondary extravascular passageway between the Anterior Interventricular Vein and the Left Anterior Descending Artery at a location downstream of the obstructed, injured or diseased-affected segment thereof; and,

iii. causing blood to flow from the Circumflex Artery, through the primary extravascular passageway, through the Great Cardiac Vein into the Anterior Interventricular Vein, and through the secondary extravascular passageway into the Left Anterior Descending Artery downstream of the

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obstructed, injured or disease-affected segment thereof.

30. The method of Claim 29 wherein step iii is accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the primary extravascular passageway.

31. The method of Claim 30 wherein step iii is further accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the secondary extravascular passageway.

32. A method for performing a medical procedure at an intracorporeal target location within a mammalian body, said method comprising the steps of:

a) positioning, within a blood vessel a catheter device which comprises:

i) a flexible catheter body having a proximal end and a distal end;

ii) a tissue-penetrating element passable out of a first location on said catheter body to form an extravascular passageway which extends from the blood vessel in which the catheter is positioned to an intracorporeal target location outside of said blood vessel;

b) orienting the first location of the catheter body relative to the intracorporeal target location such that the tissue-penetrating element may pass out of the first location of the catheter body to form an extravascular passageway between said blood vessel and said intracorporeal target location;

c) passing the tissue-penetrating element out of the catheter body to form said extravascular passageway between said blood vessel and said intracorporeal target location; and,

d) passing at least one procedure-performing apparatus through said extravascular passageway and

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utilizing said procedure-performing apparatus to perform said medical procedure at said intracorporeal target location.

33. The method of Claim 32 wherein said medical
5 procedure is the delivery of a flowable substance, and wherein said procedure-performing apparatus comprises a tubular cannula through which said flowable substance may be passed into said extravascular location.

34. The method of Claim 32 wherein said medical
10 procedure is the implantation of an implantable drug delivery apparatus, and wherein said procedure-performing apparatus is an implantation device for passing said drug delivery apparatus through said extravascular passageway and for implanting said delivery apparatus at said
15 extravascular location.

35. The method of Claim 32 wherein said medical
procedure is the implantation of radioactive matter for radiotherapy, and wherein said procedure-performing
20 apparatus is an implantation apparatus operative to pass said radioactive matter through said extravascular passageway and to implant said radioactive matter at said extravascular location.

36. The method of Claim 32 wherein said medical
25 procedure is the implantation of a stimulator apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said stimulator apparatus through said extravascular passageway and for implanting said stimulator apparatus at said
30 extravascular location.

37. The method of Claim 32 wherein said medical
35 procedure is the implantation of a sensor apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said sensor apparatus through said extravascular passageway and for implanting said sensor apparatus at said extravascular location.

38. The method of Claim 32 wherein said medical
procedure is the implantation of a electrode apparatus

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deployed to an operative configuration to impart structural support to at least one anatomical structure located at said extravascular location.

44. The method of Claim 32 wherein said medical procedure is the implantation of a marker apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said marker apparatus through said extravascular passageway and for implanting said marker apparatus at said extravascular location.

45. The method of Claim 44 wherein said marker is formed of radiographically visible material.

46. The method of Claim 32 wherein said medical procedure is tissue ablation, and wherein said procedure-performing apparatus is a tissue ablating apparatus.

47. The method of Claim 32 wherein said medical procedure is tissue destruction, and wherein said procedure-performing apparatus is a tissue destruction apparatus.

48. The method of Claim 32 wherein said medical procedure is tissue cutting, and wherein said procedure-performing apparatus is a tissue cutting apparatus.

49. The method of Claim 48 wherein the medical procedure is transection of a nerve, and wherein said procedure-performing apparatus is a nerve-transecting apparatus.

50. The method of Claim 32 wherein the medical procedure is the sampling of a biological fluid, and wherein said procedure-performing apparatus is a cannula through which a sample of biological fluid may be aspirated from said extravascular location.

51. The method of Claim 32 wherein the medical procedure is a sampling of solid matter, and wherein said procedure-performing apparatus is an apparatus for removing a sample of solid matter from said extravascular location.

52. The method of Claim 51 wherein said medical procedure is a tissue biopsy, and wherein said procedure-

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performing apparatus is a biopsy tool operative to sever and retrieve a segment of tissue from said extravascular location.

53. The method of Claim 32 wherein said method
5 further comprises:

withdrawing said catheter from the vasculature following performance of said medical procedure.

54. The method of Claim 32 further comprising:

10 positioning a tubular cannula within said
extravascular passageway and causing said tubular
cannula to remain indwelling within said
extravascular passageway following extraction and
removal of said catheter.

55. The method of Claim 54 wherein said indwelling
15 tubular cannula extends from said extravascular location
to an intracorporeal location, so as to drain fluid from
said extravascular location to said second location.

56. The method of Claim 54 wherein said indwelling
20 tubular cannula is accessible from any extracorporeal
location to permit desired matter to be delivered through
said cannula to said extravascular location.

57. The method of Claim 56 wherein said cannula
extends through said extravascular passageway, and
through the vasculature, and is coupled to a subcutaneous
25 injection port which is accessible from an extracorporeal
location, to allow flowable matter to be percutaneously
injected into said injection port and delivered to said
extravascular location through said indwelling cannula.

58. The method of Claim 53 wherein said method
30 further comprises:

closing the opening in the blood vessel from
which said extravascular passageway was formed,
following completion of said medical procedure.

59. The method of Claim 58 wherein the closing of
35 said opening in the blood vessel is carried out by the
deployment of a blood vessel wall closing apparatus
selected from the group of apparatus consisting of:

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an energy-emitting device;
a cautery device;
a suturing device;
a stapling device;
an endovascular graft;
a stented endovascular graft;
a balloon;
a coil;
strands of coagulation producing materials;
microfibrillar collagen;
collagen sponge;
cellulose gel; and,
combinations thereof.

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60. A catheter device insertable into a blood vessel and useable to form an extravascular passageway which extends through the wall of the blood vessel in which the catheter device is inserted, to an intracorporeal target location, said catheter device comprising:

a flexible catheter body having a proximal end and distal end;

a tissue-penetrating element passable out of a first location on the catheter body to form said extravascular passageway; and,

orientation means for determining at least the rotational orientation of the catheter body to facilitate proper positioning of the first location on the catheter body such that subsequent passage of the tissue-penetrating element from the catheter body will form said extravascular passageway between said blood vessel and said intracorporeal target location.

61. The device of Claim 60 wherein said first location is an outlet aperture formed in the distal end of said catheter body and said tissue penetrating element is passable out of said outlet aperture, and wherein said tissue-penetrating element is adapted to bend in a first

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direction as it passes out of said outlet aperture formed in the distal end of said catheter body, to thereby penetrate the wall of the blood vessel in which the catheter has been inserted.

5 62. The device of Claim 60 wherein said first location is an outlet aperture formed in the side wall of the catheter body, and wherein said tissue-penetrating element, when passed out of said outlet aperture located in the side wall of said catheter body will penetrate
10 through the wall of the blood vessel into which the catheter has been inserted.

63. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate, pliable needle having a sharp distal tip and a pre-bent resilient spine member positioned therewithin, said spine member being
15 operative to cause said pliable needle to bend in said first direction.

64. The device of Claim 60 wherein said tissue-penetrating element is an elongate member which
20 comprises:

- i) a pliable proximal shaft having a distal end, and
- ii) a sharpened tip member formed of rigid material and mounted on the distal end of said
25 pliable proximal shaft.

65. The device of Claim 60 wherein said tissue-penetrating element comprises a resilient, pre-bent member having a sharpened distal tip.

66. The device of Claim 65 wherein said needle is
30 formed of a material which is superelastic when inserted within the mammalian body.

67. The device of Claim 66 wherein said super elastic material is a nickel-titanium alloy.

68. The device of Claim 66 wherein said pre-bent
35 resilient member is a hollow needle having a hollow lumen extending longitudinally therethrough.

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69. The device of Claim 66 wherein said pre-bent resilient member is a solid needle.

70. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having
5 a trocar tip formed on the distal end thereof, in combination with a tubular sheath disposed around said needle member and longitudinally moveable relative to said needle member.

71. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having
10 an energy-emitting distal tip formed thereon, said energy-emitting distal tip being operative to emit energy which will facilitate penetration of said tissue-penetrating element through tissue.

72. The device of Claim 60 wherein the energy-emitting distal tip on said tissue-penetrating element is selected from the group of energy-emitting apparatus
15 consisting of:

20 a resistance-heated tip;
a monopolar electrocautery tip;
a bipolar electrocautery tip;
an ultrasound-emitting tip member; and,
possible combinations thereof.

73. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having
25 a distal end with a rotating tissue-severing apparatus formed thereon.

74. The device of Claim 60 wherein said tissue-penetrating element is a flow of energy passable out of
30 said outlet opening formed in said catheter body.

75. The device of Claim 60 wherein said flow of energy is selected from the group of energy types consisting of;

35 laser light;
heat;
ultrasound; and,
possible combinations thereof.

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76. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having a lumen extending longitudinally therethrough, said lumen being connectable to a source of negative pressure so as to draw tissue into said lumen through the distal end of said tissue-penetrating element.

77. The device of Claim 60 wherein said tissue-penetrating element comprises:

a pre-bent resilient, tubular sheath having an open distal end; and,

an elongate member having a sharpened distal tip, said elongate member being disposed within said tubular sheath and advanceable therethrough, such that the sharpened distal tip will emerge out of the open distal end of the sheath;

said elongate member being constructed of material which is sufficiently pliable to conform to the pre-bent configuration of the tubular sheath.

78. The device of Claim 60 further comprising:

a side car apparatus connected to at least a distal portion of the flexible catheter body, said side car apparatus being configured to received therewithin an imaging catheter such that the imaging catheter may be utilized to observe passage of the tissue-penetrating element out of the first location on the catheter body.

79. The device of Claim 78 wherein said side car is formed of a material which is at least partially impermeable to the energy utilized by the imaging device, and wherein said side car further comprises:

a window formed in said side car immediately adjacent said first location on the catheter body to permit said imaging device to observe the passage of said tissue-penetrating element out of said first location on the catheter body and through the wall of the blood vessel in which the catheter is positioned.

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80. The device of Claim 79 wherein said window is positioned in alignment with the direction in which said tissue-penetrating element will pass during creation of said extravascular passageway;

5 said window thereby comprising at least a portion of said orientation means, the orientation of the first location on said catheter body being thereby controllable by rotating the catheter device until an imaging apparatus positioned within the
10 side car is able to view the target area into which the passageway is to be formed, thereby ensuring that the catheter device is in proper rotational orientation prior to advancement of the tissue-penetrating element out of the outlet aperture.

15 81. The device of Claim 60 wherein the catheter body is formed of a flexible plastic material, and wherein a rigid tubular reinforcement member is disposed about a portion of the lumen of said catheter body, adjacent the outlet aperture, to prevent the tissue-penetrating element from resting in contact with the
20 pliable plastic material of the catheter body when the tissue-penetrating element is retracted into the catheter body.

25 82. The device of Claim 60 further comprising:
 a handpiece mounted on the proximal end of said catheter body, said handpiece having an actuator button which is connected to said tissue-penetrating element, said actuator button being advanceable in a first direction to advance said tissue-penetrating
30 element out of said outlet aperture, and retractable in a second direction to retract said tissue-penetrating element into the lumen of said catheter body.

35 83. A system comprising the passageway-forming catheter device of Claim 60 further in combination with:
 an imaging apparatus which is usable in conjunction with said orientation means to further

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facilitate the proper positioning of the first location on the catheter body.

84. The system of Claim 83 wherein said imaging apparatus is selected from the group of imaging apparatus
5 consisting of:

ultrasonic imaging apparatus;
Doppler imaging apparatus;
radiographic imaging apparatus;
magnetic resonance imaging apparatus;
10 electromagnetic imaging apparatus; and,
possible combinations thereof.

85. The system of Claim 84 wherein said apparatus is an imaging catheter.

86. The system of Claim 85 wherein the passageway-
15 forming catheter device further comprises a side car apparatus connected to at least a distal portion of the flexible catheter body, said side car apparatus being configured to receive the imaging catheter therewithin, such that the imaging catheter may be utilized to observe
20 the passage of the tissue-penetrating element from the first location on the catheter body; and,

said imaging catheter being positioned at least partially within said side car apparatus.

85. The system of Claim 84 wherein said side car
25 apparatus is formed of a material which is at least partially and permeable to the energy utilized by the imaging catheter, and wherein said side car apparatus further comprises:

a window formed in said side car apparatus
30 immediately adjacent said first location on the catheter body to permit said imaging catheter to observe the passage of the tissue-penetrating element out of the first location on the catheter body and through the wall of the blood vessel in
35 which the catheter body is positioned; and,

said imaging catheter being located within said side car adjacent said window so as to limit the

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field observed by said imaging catheter to that which is observable through said window.

86. The system of Claim 85 wherein said passageway-forming catheter device is torqueable such that said catheter device may be volitionally rotated until the imaging catheter is able to view the target area through said window, thereby ensuring that the first location on the catheter body is in the correct rotational position prior to passage of the tissue-penetrating element out of the first location on said catheter body.

87. The system comprising the catheter device of Claim 58 wherein the tissue-penetrating element comprises an elongate member having guide wire lumen extending longitudinally therethrough such that a guide wire may be advanced through said lumen upon formation of said extravascular passageway by said tissue-penetrating element, said system comprising:

said catheter device of Claim 58 further in combination with an elongate flexible guide wire which is passable through said guide wire lumen of said tissue-penetrating element.

88. A longitudinal compression apparatus useable to longitudinally compress tissue surrounding openings formed in first and second tubular anatomical conduits having lumens, wherein said first and second tubular anatomical conduits are in side-to-side juxtaposition to one another such that said openings are in alignment with one another, said longitudinal compression apparatus comprising:

a first portion positionable in abutment with the luminal surface of the first tubular anatomical conduit surrounding the opening therein;

a second portion positionable in abutment with the luminal surface of the second tubular anatomical conduit surrounding the opening formed therein;

means for connecting said first and second portions to each other, so as to longitudinally

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compress the tissue which surrounds the aligned openings of the first and second anatomical conduits and any extravascular tissue interposed therebetween.

5 89. The longitudinal compression apparatus of Claim 88 wherein said first and second portions comprise annular members positionable in abutment with said luminal surfaces.

10 90. The longitudinal compression apparatus of Claim 88 wherein first and second portions comprise opposite ends of elongate wire members formed in a cylindrical array and extending through said first and second openings, said opposite ends of said wire members being outwardly bent so as to abut against and engage the
15 luminal surfaces of said first and second anatomical conduits.

20 91. The longitudinal compression apparatus of Claim 90 wherein said wire members are pre-bent resilient wire members which, when positioned within said first and second openings and relieved of external constraint, will assume said bent configuration.

25 92. The longitudinal compression apparatus of Claim 90 wherein said wire members are plastically deformable, and wherein said device further comprises a pressure-exerting tool which is operative to bend the opposite ends of said wire members after said wire members have been positioned within said first and second openings.

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